§ 101.42

shall be placed beneath "Amount Per Serving" and above the bar.

* * * * *

(vi) When no percent is given for sugars, vitamin K, chloride, chromium, fluoride, manganese, molybdenum, or selenium, an asterisk shall be placed in the "% Daily Value" column that shall refer to another asterisk that is placed at the bottom of the nutrition label and is followed by the statement "Daily Value not established."

* * * * *

2. At 61 FR 8779, Mar. 5, 1996, in §101.36, paragraph (b)(3)(v) was amended by removing the words "folate (folacin)" and by adding in their place the words "folate—either folic acid or folacin may be used", effective April 19, 1996

§101.42 Nutrition labeling of raw fruit, vegetables, and fish.

- (a) The Food and Drug Administration (FDA) urges food retailers to provide nutrition information, as provided in §101.9(c), for raw fruit, vegetables, and fish at the point-of-purchase. If retailers choose to provide such information, they should do so in a manner that conforms to the guidelines in §101.45.
- (b) In §101.44, FDA has listed the 20 varieties of raw fruit, vegetables, and fish that are most frequently consumed during a year and to which the guidelines apply.
- (c) FDA has also defined in §101.43, the circumstances that constitute substantial compliance by food retailers with the guidelines.
- (d) By May 8, 1993, FDA will issue a report on actions taken by food retailers to provide consumers with nutrition information for raw fruit, vegetables, and fish under the guidelines established in §101.45.
- (1) The report will include a determination of whether there is substantial compliance, as defined in §101.43, with the guidelines.
- (2) In evaluating substantial compliance, FDA will consider only the 20 varieties of raw fruit, vegetables, and fish most frequently consumed as identified in §101.44.
- (e) If FDA finds that there is substantial compliance with the guidelines for the nutrition labeling of raw fruit and vegetables or of fish, the agency will so

state in the report, and the guidelines will remain in effect. FDA will reevaluate the market place for substantial compliance every 2 years.

(f) If FDA determines that there is not substantial compliance with the guidelines for raw fruit and vegetables or for raw fish, the agency will at that time issue proposed regulations requiring that any person who offers raw fruit and vegetables or fish to consumers provide, in a manner prescribed by regulations, the nutrition information required by §101.9. Final regulations would have to be issued 6 months after issuance of proposed regulations, and they would become effective 6 months after the date of their promulgation.

§ 101.43 Substantial compliance of food retailers with the guidelines for the voluntary nutrition labeling of raw fruit, vegetables, and fish.

- (a) The Food and Drug Administration (FDA) will judge a food retailer who sells raw agricultural commodities or raw fish to be in compliance with the guidelines in § 101.45 with respect to raw agricultural commodities if the retailer displays or provides nutrition labeling for at least 90 percent of the raw agricultural commodities listed in § 101.44 that it sells, and with respect to raw fish if the retailer displays or provides nutrition labeling for at least 90 percent of the types of raw fish listed in § 101.44 that it sells. To be in compliance, the nutrition labeling shall:
- (1) Be presented in the store or other type of establishment in a manner that is consistent with §101.45(a);
- (2) Be presented in content and format that are consistent with $\S 101.45(b)$; and
- (3) Include data that have been provided by FDA (see §101.45(i)), that have been accepted by FDA (see §101.45 (c), (f), and (g)), or that are consistent with §101.45 (d) and (e) and have not been found to be out of compliance after a review under §101.9(e) (see §101.45(h)).
- (b) To determine whether there is substantial compliance by food retailers with the guidelines in §101.45 for the voluntary nutrition labeling of raw fruit and vegetables and of raw fish, FDA will select a representative sample of 2,000 stores, allocated by store

type and size, for raw fruit and vegetables and for raw fish.

(c) FDA will find that there is substantial compliance with the guidelines in §101.45 if it finds based on paragraph (a) of this section that at least 60 percent of all stores that are evaluated are in compliance.

(d) FDA will evaluate substantial compliance separately for raw agricultural commodities and for raw fish.

§101.44 Identification of the 20 most frequently consumed raw fruit, vegetables, and fish in the United States.

(a) The 20 most frequently consumed raw fruit are: Banana, apple, watergrape, melon, orange, cantaloupe, grapefruit, strawberry, peach, pear, nectarine, honeydew melon, plum, avocado, lemon, pineapple, tangerine, sweet cherry, kiwifruit, and lime.

(b) The 20 most frequently consumed raw vegetables are: Potato, iceberg lettuce, tomato, onion, carrot, celery, sweet corn, broccoli, green cabbage, cucumber, bell pepper, cauliflower, leaf lettuce, sweet potato, mushroom, green onion, green (snap) bean, radish, summer squash, and asparagus.

(c) The 20 most frequently consumed raw fish are: Shrimp, cod, pollack, catfish, scallop, Atlantic/coho salmon, flounder, sole, oyster, orange roughy, Atlantic/Pacific and jack mackerel, ocean perch, rockfish, whiting, clam, haddock, blue crab, rainbow trout, halibut, and lobster.

§101.45 Guidelines for the voluntary nutrition labeling of raw fruit, vegetables, and fish.

Nutrition labeling for raw fruit, vegetables, and fish listed in §101.44 should be presented to the public in the following manner:

(a) Nutrition labeling information should be displayed at the point of purchase by an appropriate means, including by affixing it to the food, by posting a sign, or by making the information readily available in brochure, notebook, or leaflet form in close proximity to the foods. The nutrition labeling information may also be supplemented by a video, live demonstration, or other media.

(b) Nutrition information should be provided on the label or in labeling in accordance with §101.9, as modified by the following guidelines:

(1) The percent U.S. RDA for protein, thiamin, riboflavin, and niacin may be declared in the nutrition labeling. Declaration of complex carbohydrates, sugars, dietary fiber, saturated fat, and cholesterol is also voluntary.

(2) Nutrition labeling information may be presented on individual labels or in charts in vertical columns or in lines. When lines are used, any subcomponents declared should be listed parenthetically after principal components (e.g., saturated fat should be parenthetically listed after fat).

(3) Declaration of the number of servings per container need not be included in nutrition labeling of raw

fruit, vegetables, and fish.

(4) The nutrition label data should be based on raw edible portion for fruit and vegetables and on a cooked edible portion for fish. The methods used to cook fish should be those that do not add fat, breading, or seasoning (e.g., salt or spices).

(c) Nutrient data and proposed nutrient values for nutrition labeling for raw fruit, vegetables, and fish may be submitted to the Center for Food Šafety and Applied Nutrition (HFS-150), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, for review and evaluation. The data and nutrient values for nutrition labeling are appropriate for use if they are accepted by the Food and Drug Administration (FDA). The submission to FDA should include information on the source of the data (names of investigators, name of organization, place of analysis, dates of analyses), number of samples, sampling scheme, analytical methods, statistical treatment of the data, and proposed quantitative label declarations. The nutrient values for the nutrition labeling should be determined in accordance with FDA guidance.

(d) Composite data that reflect representative nutrient levels for various varieties, species, cultivars; seasons; and geographic regions may be used to label raw fruit, vegetables, and fish. Alternatively, data that reflect a specific variety, species, cultivar; season; or geographic region may be used to label raw fruit, vegetables, and fish; the nutrition labeling information for such